



February 12, 2013

Dear Members of the House Health, Insurance & Environment Committee,

The Colorado BioScience Association (CBSA) encourages you to support HB 13-1121, legislation that revises state pharmacy substitution guidelines to include substitution of biosimilars for biologics. As the FDA begins review of biosimilar applications for approval in the U.S. market, it is necessary that state laws are updated to reflect these new treatments while enacting safeguards to protect patient safety.

CBSA supports updating the substitution guidelines and the patient safety provisions included in the update. By requiring pharmacists to notify patients and providers of the substitution, any adverse effect experienced by the patient can be attributed properly. Notification requirements also ensure that biosimilars are not substituted for an unapproved indication, as a biosimilar may not be approved as interchangeable by the FDA for all indications of the reference biologic.

The FDA may approve the first biosimilar application as early as this year, and state substitution policies should be updated before that time to prevent ambiguity on the part of pharmacists, physicians, and patients about which treatments are accessible.

We look forward to working on this issue.

Sincerely,

A handwritten signature in black ink, appearing to read "April Giles". The signature is fluid and cursive, with the first name "April" and last name "Giles" clearly distinguishable.

April Giles
President and CEO
Colorado BioScience Association